Evita 2 dura
Ventilation Plus

Addendum to
Evita 2 dura
Operating Instructions

Dräger

NOTICE

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Contents

Important Safety Information

Operator's Responsibility for Patient Safety

For correct and effective use of the product and in order to avoid hazards it is mandatory to carefully read and to observe all portions of this manual.

The design of the intensive care ventilators this product is intended to be used with, accompanying literature, and the labeling on the equipment take into consideration that the purchase and use of the equipment are restricted to trained professionals, and that certain inherent characteristics of the equipment are known to the trained operator. Instructions, warnings, and caution statements are limited, therefore, largely to the specifics of the Draeger design. This publication excludes references to various hazards which are obvious to a medical professional and operator of respiratory care equipment, to the consequences of misuse of such equipment, and to potentially adverse effects in patients with abnormal conditions. Product modification or misuse can be dangerous. Draeger Medical, Inc. disclaims all liability for the consequences of product alterations or modifications, as well as for the consequences which might result from uses of the product not covered by its intended use or from the combination of this product with other products whether supplied by Draeger or by other manufacturers if such a combination is not endorsed by Draeger Medical, Inc..

The operators of ventilator systems must recognize their responsibility for choosing appropriate safety monitoring that supplies adequate information on equipment performance and patient condition. Patient safety may be achieved through a wide variety of different means ranging from electronic surveillance of equipment performance and patient condition to simple, direct observation of clinical signs. The responsibility for the selection of the best level of patient monitoring lies solely with the equipment operator.

Limitation of Liability

Draeger Medical, Inc.'s liability, whether arising out of or related to manufacture and sale of the goods, their installation, demonstration, sales representation, use, performance, or otherwise, including any liability based upon Draeger Medical, Inc.'s Product Warranty, is subject to and limited to the exclusive terms and conditions as set forth, whether based upon breach of warranty or any other cause of action whatsoever, regardless of any fault attributable to Draeger Medical, Inc. and regardless of the form of action (including, without limitation, breach of warranty, negligence, strict liability, or otherwise).

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Draeger Medical, Inc. shall not be liable for, nor shall buyer be entitled to recover any special incidental, or consequential damages or for any liability incurred by buyer to any third party in any way arising out of or relating to the goods.

Warranty

All Draeger products are guaranteed to be free of defects for a period of one year from date of delivery. The following are exceptions to this warranty:

1. The defect shall be a result of workmanship or material. Defects caused by misuse, mishandling, tampering, or by modifications not authorized by Draeger Medical, Inc. or its representatives are not covered.

2. Rubber and plastic components and materials are-warranted to be free of defects at time of delivery.

3. Oxygen sensors capsules have a six-month limited warranty from the date of delivery.

Any product which proves to be defective in workmanship or material will be replaced, credited, or repaired with Draeger Medical, Inc. holding the option. Draeger Medical, Inc. is not responsible for deterioration, wear, or abuse. In any case, Draeger Medical, Inc. will not be liable beyond the original selling price.

Application of this warranty is subject to the following conditions:

1. Draeger Medical, Inc. or its authorized representative must be promptly notified, in writing, upon detection of the defective material or equipment.

2. Defective material or equipment must be returned, shipping prepaid, to Draeger or its authorized representative.

3. Examination by Draeger Medical, Inc. or its authorized representative must confirm that the defect is covered by the terms of this warranty.

4. Notification in writing, of defective material or equipment must be received by Draeger Medical, Inc. or its authorized representative no later than two (2) weeks following expiration of this warranty.

In order to assure complete protection under this warranty, the Customer Registration Card and/or Periodic Manufacturer's Service Record (if applicable) must be returned to Draeger within ten (10) days of receipt of the equipment.

The above is the sole warranty provided by Draeger Medical, Inc. No other warranty expressed or implied is intended. Representatives of Draeger are not authorized to modify the terms of this warranty.

Draeger Medical, Inc., Telford, PA

Operating Instructions Evita 2 dura Ventilation Plus

Definitions

General WARNINGS and CAUTIONS

WARNING !

A WARNING statement refers to conditions with a possibility of personal injury if disregarded.

CAUTION !

A CAUTION statement designates the possibility of damage to equipment if disregarded.

NOTE: A NOTE provides additional information intended to avoid inconveniences during operation.

Inspection	=	examination of actual condition
Service	=	measures to maintain specified condition
Repair	=	measures to restore specified condition
Maintenance	=	inspection, service, and repair, where necessary
Preventive Maintenance	=	Maintenance measures at regular intervals

Typing conventions in this manual

Controls ("hard" keys and screen keys / fields) are designated as »**Control Name**«, e.g.

»**Menu Mode**«

Screen pages are indicated as »**Screen page**«, e.g.

»**Alarm limits**«

On-screen messages are printed in **bold**, e.g.

SpO2 measurement is activated.

WARNING !

Strictly follow Operator's Instruction Manuals

Any use of the product requires full understanding and strict observation of all portions of these instructions as well as the Operating Instructions of the Evita 2 dura ventilator. The equipment is only to be used for the purpose specified under "Intended Use" (page 8). Observe all WARNINGS and CAUTIONS as rendered throughout the manuals and on labels on the equipment.

WARNING !

DANGER, risk of explosion if used in the presence of flammable anesthetics.

The equipment is neither approved nor certified for use in areas where combustible or explosive gas mixtures with air or with nitrous oxide are likely.

WARNING !

Electrical connections to equipment which is not listed in these Operating Instructions should only be made following consultations with the respective manufacturers or a qualified expert.

WARNING !

Installation of the Evita 2 dura Ventilation Plus Option may be performed by factory trained and authorized service personnel only.

Precautions During Maintenance

CAUTION !

Restriction of Distribution

Federal Law and Regulations in the United States and Canada restrict this device to sale by or on the order of a physician.

WARNING !

To avoid any risk of infection, clean and disinfect ventilator and accessories before any maintenance according to established hospital procedures - this applies also when returning ventilators or parts for repair.

CAUTION !

Traceability

Federal Law in the United States requires traceability of this equipment. Please return the self addressed registration card included with the product and fill in the required information.

WARNING !

Preventive Maintenance work on the Evita 2 dura ventilator and its components may be performed by trained and factory authorized staff only.

CAUTION !

Accessories

Use only accessories listed in the Ordering Information (page 23).

WARNING !

Never operate the ventilator if it has suffered physical damage or does not seem to operate properly. In this case always refer servicing to properly trained and factory authorized service personnel.

Precautions During Operation

CAUTION !

Maintenance

In case of malfunction of this device, contact your local DraegerService or our Factory Authorized Technical Service Center.

The device must be inspected and serviced (preventive maintenance) by competent and factory authorized technical service representatives at regular 6 month intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract through your vendor.

Maintenance or repair of the Evita 2 dura ventilator and its installed options shall be performed only by Draeger authorized technical service representatives.

WARNING !

Only use a combination of 2 Evita ventilators to perform independent lung ventilation.

Other combinations are not approved nor endorsed by Draeger for use with ILV.

WARNING !

On the Slave ventilator, the rate setting »f« does not have any direct effect during ILV. However, as a safety precaution »f« should be set to the same value as that ot the Master ventilator. This will ensure that the two lung compartments are not ventilated at different rates in case the connection between the two ventilators is broken.

WARNING !

When using AutoFlow, always set the alarm limit »Paw ⌐« in order to generate an alarm in the event of an increase in airway pressure with reduced compliance.

Intended Use

Ventilation Plus

Option for Evita 2 dura providing the intensive care ventilator with the following additional ventilation modes:

– **AutoFlow**®
  For automatically optimizing inspiratory flow in combination with volume controlled ventilation modes CMV, SIMV and MMV.

– **APRV** (**A**irway **P**ressure **R**elease **V**entilation)
  Spontaneous breathing on two pressure levels with long time ranges – independently adjustable

– **ILV**
  Independent **L**ung **V**entilation,
  Separate, differential, synchronized ventilation with two Evita ventilators.

Installation

> **WARNING !**
>
> **Installation of the Evita 2 dura Ventilation Plus option may be performed by factory trained and authorized service personnel only.**

Optional modes provided by Evita 2 dura Ventilation Plus are ready for use.

Operation

Using AutoFlow®

Supplement to the volume controlled ventilation modes
CMV, SIMV and MMV.

AutoFlow – for automatically optimizing inspiratory flow.
AutoFlow* decelerates and adjusts inspiratory flow in
such a way that a minimum airway pressure results for a
selected tidal volume V_T and a given patient lung
compliance, thus avoiding pressure peaks.
Evita 2 dura delivers additional inspiratory flow during
spontaneous patient inspirations - limited by the alarm
limit V_{Ti} ⌐̸ .
The patient can also exhale during the inspiratory plateau.
Inspiratory pressure is limited by the alarm limit Paw ⌐̸ .

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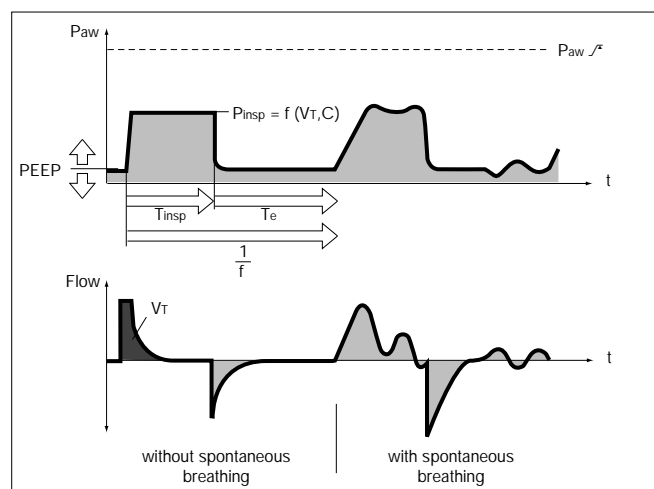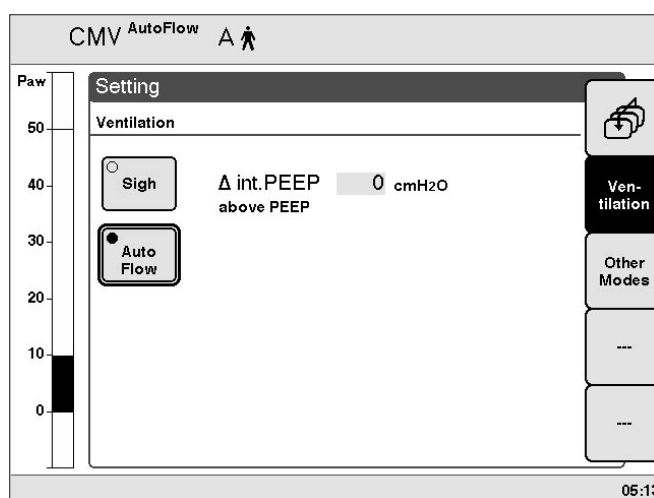
Setting **AutoFlow**

● Press menu key »**Settings**«.
  The »Ventilation« menu screen appears.

Display example:

● Select screen key »**AutoFlow**« = turn dial knob,

● Activate function »**AutoFlow**« = press dial knob.

  Black dot appears in key = function activated.

  Additionally, the word **AutoFlow** appears in the status
  line

———————————————————————————————————————

> ### WARNING !
>
> **When using AutoFlow, always set the alarm
> limit »Paw ⌐̸ « in order to generate an alarm in
> the event of an increase in airway pressure
> with reduced compliance.**

AutoFlow may be used in SIMV and MMV modes in the
same fashion.

————————————————————————————————

* See page 20 for a detailed description of AutoFlow.

Using APRV
Airway **P**ressure **R**elease **V**entilation

Free spontaneous breathing at an elevated CPAP pressure level and a brief period of low pressure (release).

For spontaneously breathing patients who need assistance with CO_2 removal.

Ventilation mode APRV can be set in an APRV-specific menu and configured while in menu mode.

Set ventilation pattern for APRV with the following ventilation parameters:
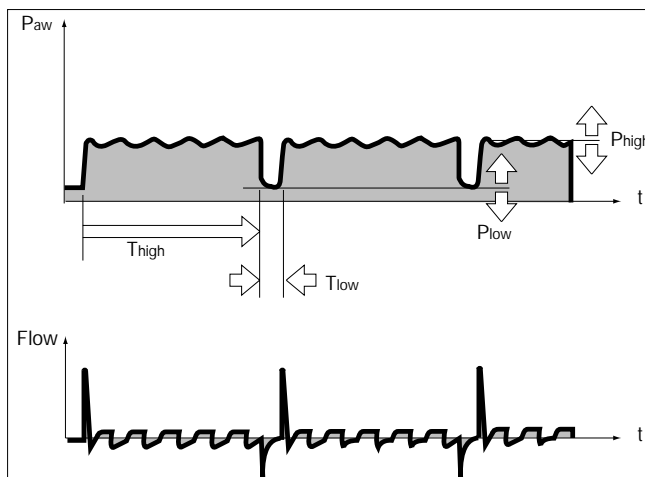
Inspiratory time »T_{high}«
Expiratory time »T_{low}«

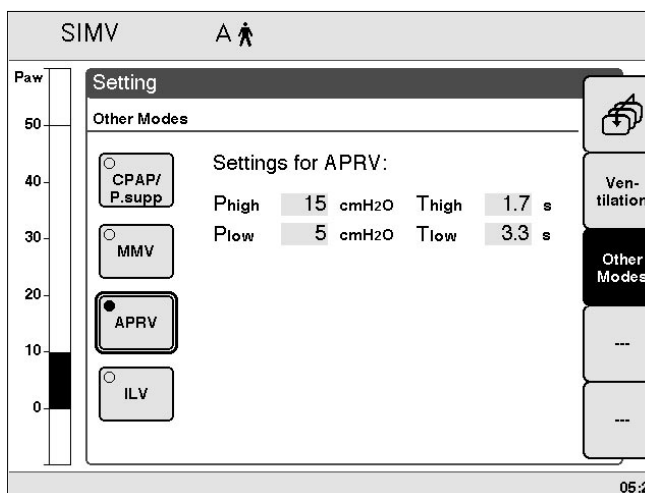Inspiratory pressure »P_{high}«
Pos. endexp. pressure »P_{low}«

O_2 concentration »O_2«
Pressure rise time »**Slope**«

———————————————————————————————

Programming APRV to »**Other Modes**« key:

● Press menu key »**Settings**«.

● Press menu key »**Other Modes**«.

● Select screen key »**APRV**« = turn dial knob.
Confirm = press dial knob.

The »**Other Modes**« key is now programmed for ventilation mode »**APRV**«: This is indicated in the information status line at the bottom right of the screen.

————————————————————————————————

The following ventilation parameters are set in the APRV screen menu:

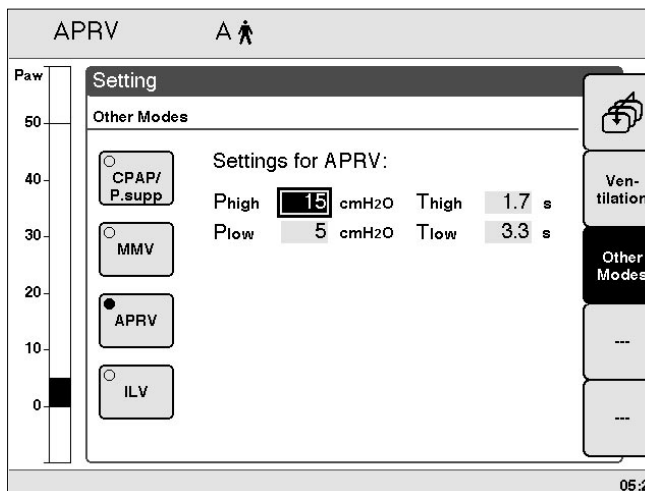Inspiratory pressure »P_{high}«
Positive endexpiratory pressure »P_{low}«

Inspiratory time »T_{high}«
Expiratory time »T_{low}«

Example: to set »P_{high}«.

● Select field »P_{high}« = turn dial knob.
Confirm = press dial knob.

● Set value = turn dial knob.
Confirm = press dial knob.

»P_{low}«, »T_{high}«, »T_{low}« are set in the same fashion.

————————————————————————
* See page 22 for a detailed description of APRV.

Their O_2 concentration »**O2**« and pressure rise »**Slope**« are set directly via the parameter keys.

To activate mode »**APRV**«:

● Press key »**Other Modes**«.

APRV can be expanded to include the supplement "Apnea ventilation":

Apnea ventilation – for changing over automatically to volume-controlled mandatory ventilation if an apnea occurs.
If an apnea occurs, Evita 2 dura generates an alarm upon expiry of the set alarm time (T_{apnea} ╱⸱) and starts volume controlled ventilation with the set ventilation parameters:
Frequency »**fApnea**«
Tidal volume »**VTApnea**«

––

Set apnea ventilation:

● Press menu key »**Settings**«.

● Select screen key »**Apnea ventil.**« = turn dial knob.
Activate **apnea ventilation** = press dial knob.
A black dot appears in the key when apnea ventilation is active.

● Select screen key »**VTApnea**« = turn dial knob.
Confirm = press dial knob.

● Set value = turn dial knob.
Confirm = press dial knob.

● Set value for »**fApnea**« accordingly.

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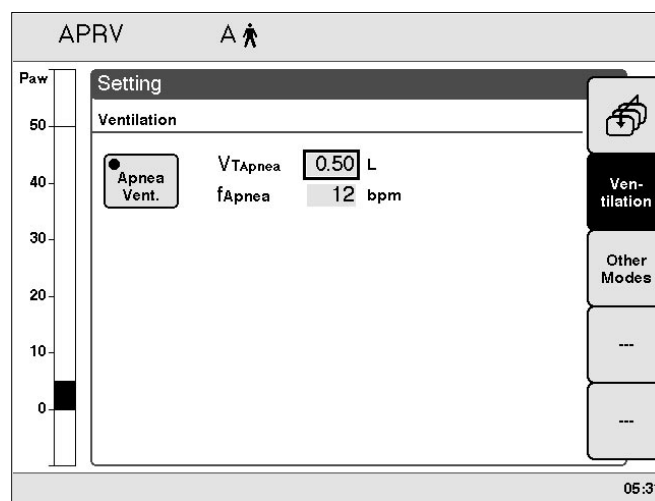
Using ILV
ILV = **I**ndependent **L**ung **V**entilation

Synchronous ventilation with two separate Evita ventilators connected via analog interfaces.

The two units operate in master-slave mode with the master unit taking control.

NOTE: ILV can be used only used with CMV ventilation mode.

The following device combinations may be used:

– Two Evita 2 dura in combination

– Evita 2 dura combined with Evita 4

– Evita 2 dura combined with Evita 2

– Evita 2 dura combined with Evita.

WARNING !

Only use a combination of 2 Evita ventilators to perform independent lung ventilation.

Other combinations are not approved nor endorsed by Draeger for use with ILV.


Prerequisites for the combination

– If an Evita ventilator is used, it must have analog interface EvitaBus (option) installed.

– Connecting cable 84 11 794 for connecting Evita 2 dura to another Evita 2 dura or to Evita 4.

– Connecting cable 84 11 793 for connecting Evita 2 dura to Evita 2 or to Evita.
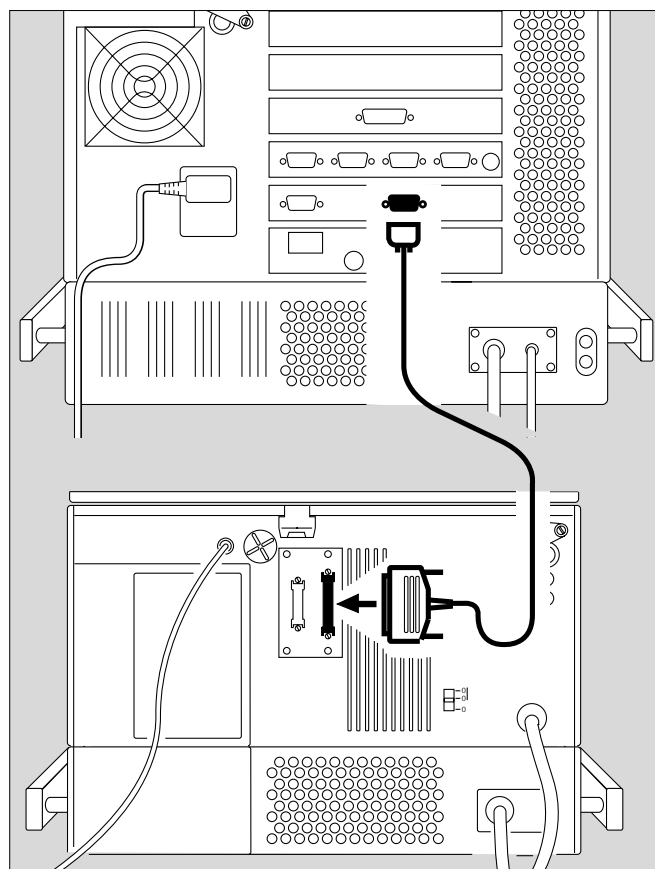
Preparation

For Evita 2 dura - Evita 2 dura
and
Evita 2 dura - Evita 4:

● Connect both Evita's via their ILV ports with cable 84 11 794.

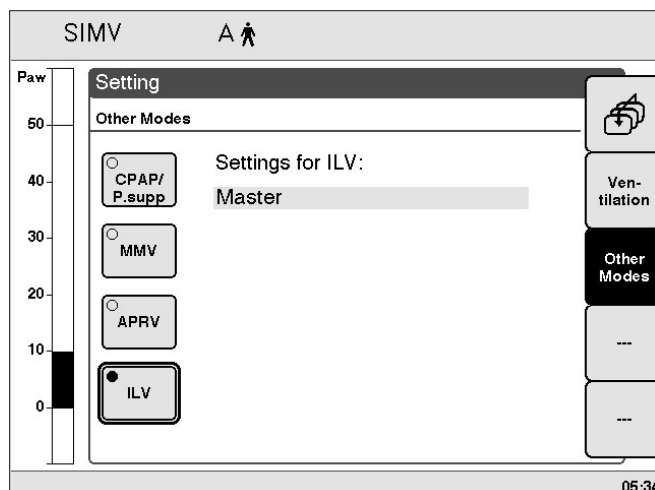Operating Instructions Evita 2 dura Ventilation Plus
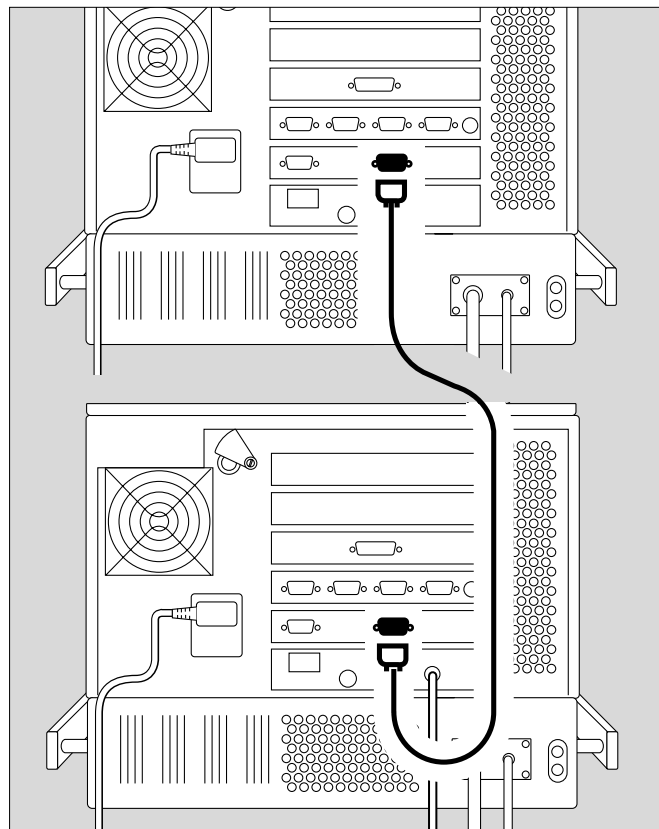
Evita 2 dura - Evita:

● Connect the two ventilators via ILV port (Evita 2 dura) and analog interface port (Evita) with cable 8411793.
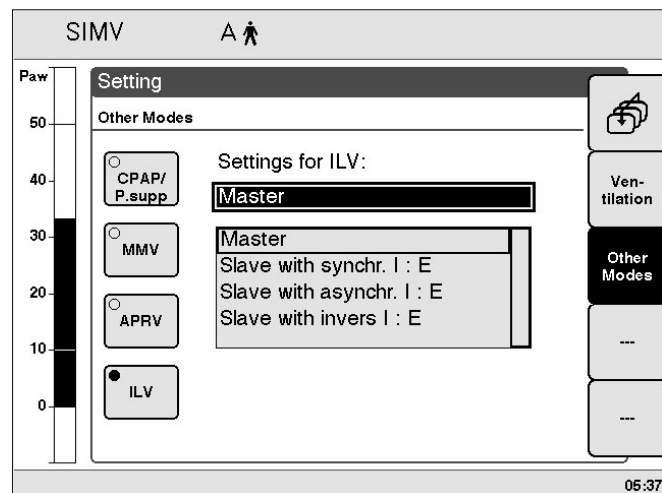
Programming ILV to »Other Modes« key

● Press menu key **»Settings«**.

● Press menu key **»Other Modes«**.

● Select screen key **»ILV«** = turn dial knob. Confirm = press dial knob.

Setting »Master« or »Slave« status

On Evita 2 dura = Master:

● Press menu key »**Settings**«.

● Press menu key »**Menu Mode**«.

● Select »**Master...**« or »**Slave...**« = turn dial knob
  Confirm = press dial knob.

Master with trigger

Inspiration is controlled by the spontaneous breathing
cycle of the lung compartment ventilated by the Master
unit, as in the assisted ventilation mode CMV/Assist.

Activate the trigger on the Master unit:

● Press parameter key »**Trigger**«,

● Set a value 0.3 to 15 L/min.

● Confirm = press dial knob.

Master without Trigger

Inspiration is time cycled, as in the controlled ventilation
mode CMV.

To deactivate trigger on Master unit:

● Press parameter key »**Trigger**«,

● Set a value less than 0.3 or greater than
  15 L/min = turn dial knob.
  Display: **– – –**
  Trigger is deactivated.

● Confirm = press dial knob.

● **Do not activate ILV yet!**

On the Slave unit

If the second ventilator is an Evita 4 or Evita, refer to their respective Operating Instructions for information on settings.

If the second ventilator is an Evita 2 dura, set either:

Slave-synchronous I:E:

The I:E ratio of the Slave unit is synchronized directly.

Or:

Slave-asynchronous I:E:

The begin of inspiration and the total duration of an inspiratory cycle are controlled by the Master ventilator; the I:E ratio of the Slave unit can be selected as required.

Or:

Slave-inverse I:E:

Inspiration of the Slave ventilator begins with expiration of the Master unit and expiration of the Slave begins with inspiration of the Master.
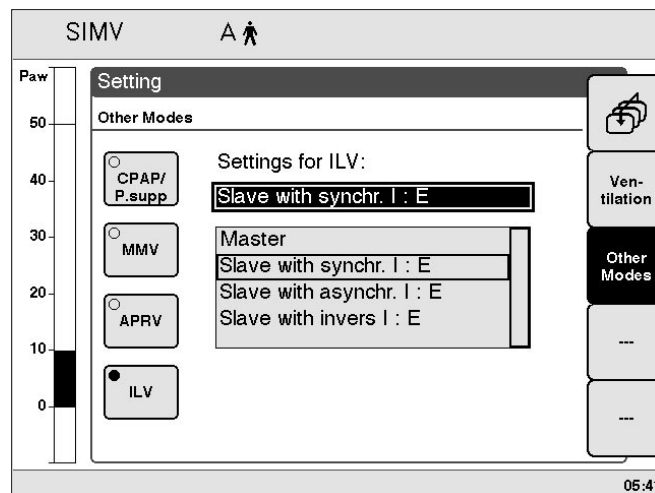
● **Do not activate ILV yet!**

On the Master unit

Set the basic ventilation pattern:

● Use the parameter keys and central dial knob:

Tidal volume »V$_T$«
Respiratory rate »f«
Inspiratory time »T$_{insp}$«
Inspiratory flow »Flow«
Positive endexpiratory airway pressure »PEEP«
O$_2$ concentration »O$_2$ vol.%«

Also: Pressure limitation »P$_{max}$« if required.

On the Slave unit

Set the basic ventilation pattern:

● As described for the Master unit, in accordance with
  its respective Instructions for Use.

WARNING !

**On the Slave ventilator, the rate setting »f«
does not have any direct effect during ILV.
However, as a safety precaution »f« should be
set to the same value as that ot the Master
ventilator. This will ensure that the two lung
compartments are not ventilated at different
rates in case the connection between the two
ventilators is broken.**

Therefore:

● Set **»f«** to the same value as on the Master unit.

Start ILV ventilation

● Press and hold the key **»Other Modes«** on both
  ventilators until the yellow indicator lights are
  continuously lit.

ILV is now effective!

● Select status page »ILV«.

● Briefly press the screen key **»Other Modes«**

● Screen display (example):
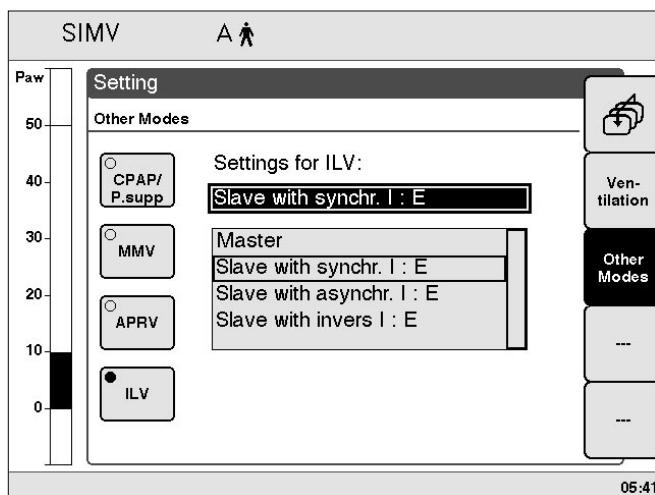
To return to the previous screen display:

2 Press screen key » ⟳ «.

Set **Sigh** (intermittent PEEP) following Evita 2 dura
Operating Instructions.

Troubleshooting

Message	Cause	Remedy
Check frequency ILV Slave ! Message on the slave device	Frequency difference of more than 12 % between the master and slave devices.	Match the slave device frequency to the master device frequency
ILV sync. inop　　　**!!!** Message on the slave device	Frequency of the master device less than 4 / min. Device defective.	Set a higher frequency. Call DraegerService

Maintenance

CAUTION !

Maintenance

In case of malfunction of this device, contact your local DraegerService or our Factory Authorized Technical Service Center.

The Evita 2 dura ventilator must be inspected and serviced (preventive maintenance) by competent and factory authorized technical service representatives at regular 6 month intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract through your vendor.

Maintenance or repair of the Evita 2 dura ventilator shall be performed only by Draeger authorized technical service representatives.

WARNING !

To avoid any risk of infection, clean and disinfect ventilator and accessories before any maintenance according to established hospital procedures - this applies also when returning ventilators or parts for repair.

WARNING !

Preventive Maintenance work on the Evita 2 dura ventilator and its components may be performed by trained and factory authorized staff only.

WARNING !

Never operate the ventilator if it has suffered physical damage or does not seem to operate properly. In this case always refer servicing to properly trained and factory authorized service personnel.

Maintenance Intervals

Preventive maintenance　Every 6 months by trained and factory authorized service personnel.

Functions of the Evita 2 dura Monitoring Plus option are inspected as part of the scheduled preventive maintenance of the Evita 2 dura ventilator every six months.

Technical Data

for the Ventilation Plus option
supplementing Technical Data found in the
Evita 2 dura Operating Instructions

APRV settings

Thigh	0.1 s to 30 s
T low	0.1 s to 30 s
Phigh	0 cmH$_2$O to 80 cmH$_2$O
Plow	0 cmH$_2$O to 35 cmH$_2$O
Slope	0 s to 2 s

Separate ILV ventilation

Master	With trigger / without trigger
Slave	Synchr. / asynchr. / inverse I:E

Description of Ventilation Modes

## Volume-controlled ventilation with PLV and AutoFlow®

AutoFlow is a new supplement optimizing inspiratory flow during mandatory ventilator breaths in the volume controlled ventilation modes CMV, SIMV, and MMV. In order to illustrate the differences, the conventional ventiation modes are briefly summarized first below:

Classic volume constant mandatory ventilator breath

In mandatory ventilation modes without AutoFlow, the parameter »Insp.Flow« restricts inspiratory flow. If the inspiratory flow is sufficiently high, the set tidal volume V_T is reached before inspiratory time Tinsp is over. The inspiratory valve will close and the supply of breathing gas supply will stop. The expiratory valve remains closed until the end of inspiratory time Tinsp. This phase, the inspiratory pause, can be identified in the P_{aw} (t) waveform as the plateau with a pressure P_{plat}.

This type of mandatory ventilator breath, which, for technical reasons, is found in the same form in almost all intensive care ventilators, has two considerable disadvantages:

– The pressure peak can lead to overdistension of individual lung areas if the lungs are extremely non-homogeneous, and

– unless the pattern of ventilation is regularly adapted to the needs of the spontaneously breathing patient, limited inspiratory flow and the closed inspiratory and expiratory valves during the inspiratory pause can cause the patient to "fight" the ventilator.
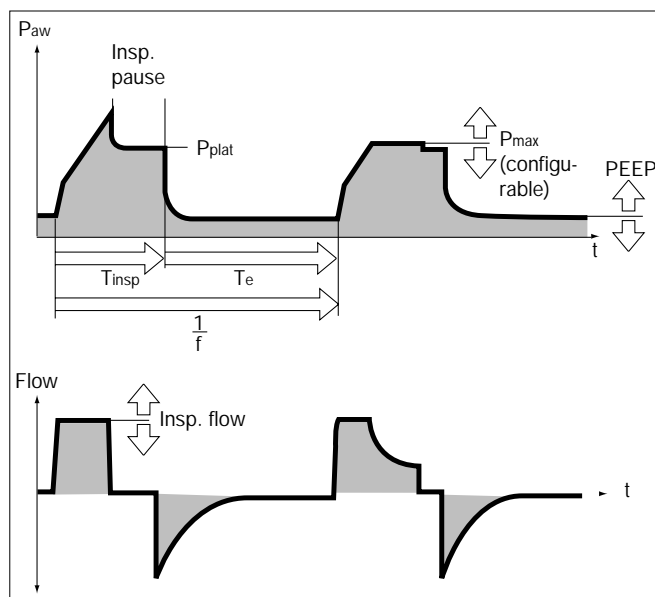
Manual pressure limit Pmax

Evita 2 dura can prevent pressure peaks while maintaining the set tidal volume V_T by setting a pressure limit P_{max}. Tidal volume V_T remains constant as long as a pressure plateau P_{plat} can be measured and the flow waveform shows a zero flow phase between inspiration and expiration.

Evita 2 dura performs this function by reducing inspiratory flow upon reaching the set value of P_{max}. If the set tidal volume V_T can no longer be filled with the selected pressure P_{max} due to reduced compliance, a "Volume not constant" alarm is automatically generated.
Manual pressure limiting can be performed with all Evita ventilator models.

AutoFlow®

AutoFlow can be activated in the» Settings« submenu. AutoFlow takes over the task of setting both "Insp.Flow" and "Pmax". The »Flow« parameter key and »Pmax« screen key are disabled or no longer displayed, respectively.

With AutoFlow, inspiratory flow is automatically adjusted to changes in lung conditions (C, R) and to the demands of the spontaneously breathing patient .

WARNING !

When using AutoFlow, always set the alarm limit »Paw ⌐« in order to generate an alarm in the event of an increase in airway pressure with reduced compliance.


Typically, the inspiratory time T_{insp} selected is much longer than the time required to fill the lungs. The minimum inspiratory pressure P_{insp} corresponds to the value calculated from the tidal volume V_T and compliance C of the lung.

Inspiratory flow is now automatically controlled so that there is no pressure peak caused by ET-tube and airway resistance. The plateau pressure P_{plat} is allowed to fluctuate with changes in compliance C, as is common with all constant volume ventilator breaths. With AutoFlow, these fluctuations occur in increments with a maximum of 3 cmH$_2$O between successive ventilator breaths.

If the tidal volume V_T is reached (inspiratory flow = 0) before inspiratory time T_{insp} has fully elapsed, the control system for the inspiratory and expiratory valves ensures that the patient can breathe in and out during the remaining inspiratory time, even during the constant pressure plateau P_{plat}.

If the patient breathes in or out during mandatory inspiration, plateau pressure P_{plat} is not changed for the duration of this ventilator breath: only inspiratory and expiratory flow are adapted to the patient's demand. Although applied tidal volume V_T may differ from the set tidal volume V_T in individual ventilator breaths, a constant tidal volume V_T is supplied on average over time,.

The alarm limit »V_{Ti} ⌐« can prevent the tidal volume V_T from being exceeded . Evita 2 dura will generate an advisory (!) if the set alarm limit is exceeded once and a warning (!!!) if it is exceeded three times in succession. Tidal volume is actively limited to the value of the alarm limit »V_{Ti} ⌐« by switching to PEEP level (expiration) when necessary.


without spontaneous   with spontaneous
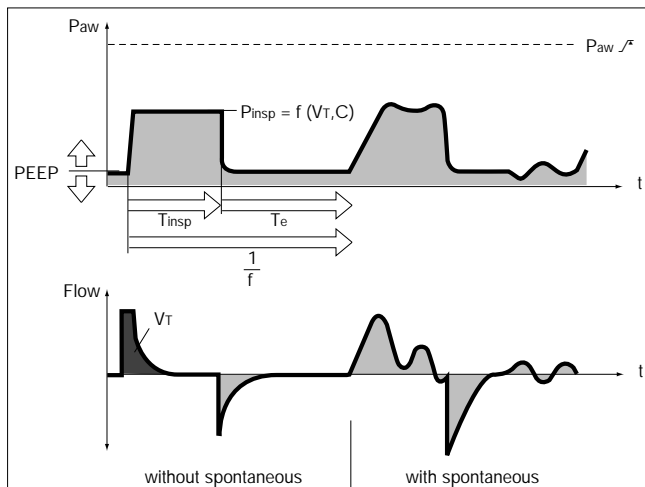
An inspiratory time T_{insp} set to a value shorter than the time required to fill the lungs can be recognized in the flow waveform: the flow at the end of inspiration will not have dropped to zero. The decision whether or not to extend inspiratory time T_{insp} in order to lower peak pressure must then be based on the current patient condition.

The effect described can also develop in the course of ventilation, e.g. due to a buildup of secretions. In this situation, pressure is limited by the alarm limit »P_{aw} ↗↟«. The pressure rise stops 5 cmH$_2$O below the alarm limit »P_{aw} ↗↟«. A »Volume not constant« alarm will only be generated when the set tidal volume V_T is not longer applied.

The start of a mandatory inspiration can be synchronized with a patient's own efforts using the adjustable flow trigger. Only while in CMV mode can the flow trigger be fully switched off (CMV Assist -> CMV).

The steepness of the pressure rise from PEEP level to the inspiration level can be even more closely adapted to the needs of the patient in SIMV and MMV modes by adjusting pressure rise time »Slope«.
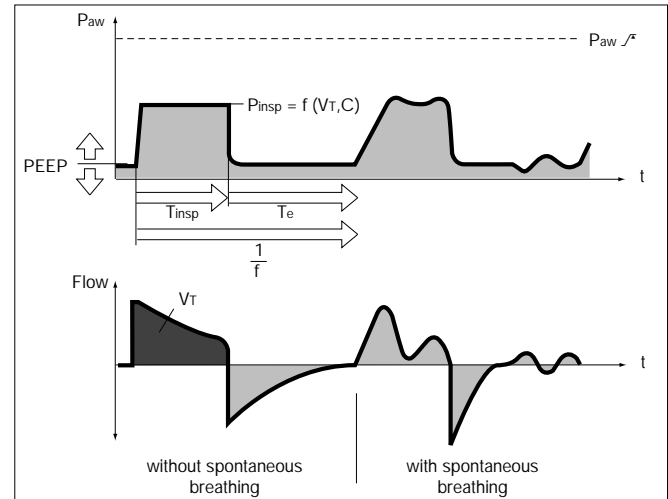
Initial ventilator response with AutoFlow

When switching on AutoFlow, Evita 2 dura applies a volume controlled ventilator breath with subsequent inspiratory pause.
The plateau pressure P_{plat} calculated for this ventilator breath serves as start-up value for inspiratory pressure with AutoFlow.

APRV

Airway **P**ressure **R**elease **V**entilation

Spontaneous breathing under continuous positive airway pressure with brief pressure release. This ventilation mode is suitable for patients with poor gas exchange. The patient breathes spontaneously at a high pressure level P_{high} of variable length T_{high}. Evita 2 dura switches to a low pressure level P_{low} for very short expiratory times T_{low}. The normal lung areas are emptied, but the "slow" lung areas only change volume to a lesser extent.

The ventilation/perfusion ratio can be improved in this way for patients with poor gas exchange.

The »Slope« setting determines the steepness of the increase from the lower pressure level to the upper pressure level. The effective time for the pressure rise cannot become greater than the set time T_{high}.
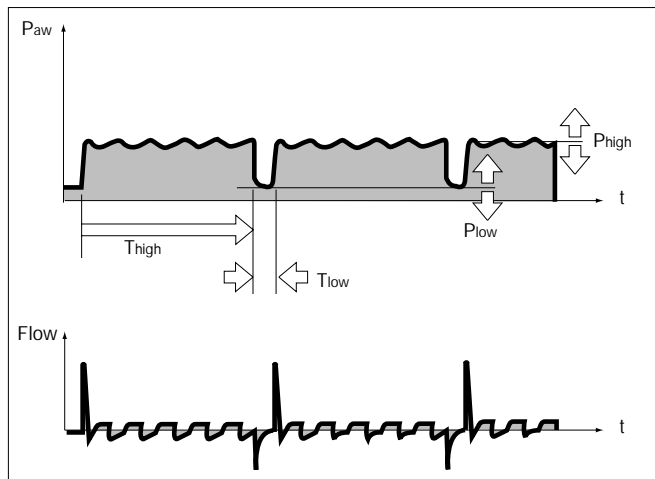
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Ordering Information

Item/Description	Part No.
"**Ventilation Plus**" option for Evita 2 dura intensive care ventilator providing ventilation modes APRV, ILV and AutoFlow®	84 13 540
Accessories	
Cable for connecting Evita 2 dura with another Evita 2 dura or Evita 4 during ILV	84 11 794
Cable for connecting Evita 2 dura with an Evita ventilator during ILV	84 11 793

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These Operating Instructions apply only to **Evita 2 dura** with Serial No.:

Without entry of a Serial No. by Draeger these Operating Instructions are provided for general information only and are not intended for use with a specific device.